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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/798,060	03/10/2004	Alec Bobroff	HM-04-PT-03-NP	5665

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EXAMINER	
GIBSON, KESHIA L	
ART UNIT	**PAPER NUMBER**
3761	

DATE MAILED: 06/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/798,060	BOBROFF ET AL.	
	Examiner	Art Unit	
	Keshia Gibson	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-13 is/are pending in the application.

4a) Of the above claim(s) 13 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-12 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-13 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 3/30/06 have been fully considered but they are not persuasive. Applicant has argued that the system of Inoue et al. appears to use only one piece of data collected during the procedure and, rather than comparing the data to other data points earlier collected in the procedure, it is then used in a mathematical formula; as a result, Applicant feels the prior art does not meet the limitations of independent Claim 1. However, Inoue et al. disclose receiving current data (collected blood amount), saving the data as historical data (previously registered weight of bag) and comparing them (through use of a formula) and activates an alarm when a predefined trend (set blood collection amount) is detected (column 8, line 20-column 9, line 11) . Thus, despite applicant's arguments, Inoue et al. are still considered to anticipate and/or render obvious the structural limitations set forth in Claims 1-12 of the claimed invention, as presented in the previous Office, and again below.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-5, 7-9, and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Inoue et al. (US 5,153,828).

In regard to Claims 1-5 and 7-9, Inoue et al. disclose a fluid monitoring and alert system 10 comprising a fluid collection device—having a drain tube 2, a vacuum reservoir 13, a suction pathway 41/others—vacuum pump (compressor) 17, sensors 40, 71, 73, a controller 18, an audible alarm 69, a visual display 12, and a valve 43 (whole document). The system records and displays data related to the system, including pressure data. The controller monitors the pressure and controls the valve so as to maintain a certain level of vacuum within the system (especially column 6, lines 13-27, column 7, lines 58-68).

In regard to Claim 11, it has been held that a recitation with respect to the manner in which a claimed invention is intended to be employed does not differentiate the claimed invention from a prior art satisfying the claimed structural limitations. *Ex parte Maham, 2 USPQ2d 1647 (1987). In re Paulsen, 30 F.3d 1475, 31 USPQ 2d 1671 (Fed. Cir. 1994).* Therefore, the system is considered capable of being used in the manner claimed.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Inoue et al.

In regard to Claim 12, Inoue et al. disclose that data, such as the amount of blood collected, is to be displayed on the visual display but do not expressly disclose the intervals at which this data is to be sampled or displayed. However, the interval at which the data is sample affects the accuracy of the information displayed to the user. As such, the interval at which data is collected and/or displayed to the user is considered to be a result effective variable. Thus, it would have been obvious to one of ordinary skill in the art to have the data display the volume of liquid collected in intervals of fifteen minutes, since it has been held that discovering an optimum value of a result effective

variable involves only routine skill in the art. *In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).*

7. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Inoue et al. in view of Killian et al. (US 5,876,387).

In regard to Claims 6, Inoue et al. disclose the claimed invention but do not expressly disclose that the vacuum reservoir is joined to a facility-wide source of suction. Killian et al. discuss a suction system to be used in a medical facility comprising a vacuum chamber and pump. Killian et al. discuss that the system is connected to a central suction facility in case of failure of the vacuum pump (column 1, lines 39-64). One would have been motivated to modify the system of Inoue et al. to have the vacuum reservoir connected to a central suction facility, as taught by Killian et al., since doing so would allow for a replacement source of suction in cause of failure of the vacuum pump. Thus, it would have been obvious to one of ordinary skill in the art to modify Killian et al. to have the vacuum reservoir connected to a facility-wide source of suction, as taught by Killian et al., since doing so would allow for a replacement source of suction in cause of failure of the vacuum pump.

8. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Inoue et al. in view of Valerio et al. (US 5,989,234).

In regard to Claim 10, Inoue et al. disclose the claimed invention but do not expressly disclose that the system comprises an autotransfusion device. Valerio et al. disclose a system for draining and collecting fluid from a body cavity comprising a vacuum pump

and chamber. Valerio et al. disclose that the device can be modified to serve as an autotransfusion device since reinfusing the patient's own blood is advantageous given today's concerns with communicable diseases (column 17, lines 22-29). (Also see Blankenship et al. US 5,116,312, column 1, lines 28-43). Thus, it would have been obvious to one of ordinary skill in the art to modify the system of Inoue et al. to comprise an autotransfusion device, as taught by Valerio et al., since doing so would provide the additional advantages of transfusion a patient with their own blood, or other bodily fluid.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Keshia Gibson whose telephone number is (571) 272-

7136. The examiner can normally be reached on M-F 8:30 a.m. - 6 p.m., out every other Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Keshia Gibson
Examiner
Art Unit 3761

klg 6/7/06

TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER